REMARKS

Claims 1-21 are pending in the application for reconsideration. The amendment simplifies the issues for appeal, it raises no new issues requiring further consideration and/or search, and it does not add matter that is unsupported by the specification. Accordingly, applicants earnestly solicit entry of the amendment.

Finality of the Office Action:

The Office Action raises a new rejection of claims 1, 2, 4, 5 and 16-20 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent 5,427,800 ("Cingotti"), which applicants made available in the IDS filed February 3, 1999. Generally, an Office Action is not made final when new rejections are raised. See MPEP § 706.07(a). In this case, the rationale for making the action final is that "amendments to the independent and dependent claims have modified the scope of the pending claims, necessitating the new grounds of rejection." Office Action at page 4. The amendment to claim 1, the only independent claim among those presently rejected, replaced the phrase "characterized in that each comprise," which is common in international claims drafting, with "comprising" to comport with standard United States claims drafting. This amendment to claim 1, being cosmetic in nature, does not change the scope of the claimed invention, as alleged by the examiner. Because the dependent claims do not protect broader subject matter than the independent claim, a prior art reference may not be applied to a dependent claim unless it also is applied to the independent claim. It follows that the new rejection cannot be predicated on changes to the scope of protected subject engendered by amendment to either the independent or dependent claims. Accordingly, the rationale for making the Office Action final is erroneous. Applicants respectfully request that the finality of this Office Action accordingly be withdrawn. In light of this request, applicants request that the Examiner not issue an Advisory Action, in the event that the Examiner maintains any of the rejections.

Rejections under 35 U.S.C. § 102:

(I) Claims 1, 5, 9, 11, and 12 are rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by WO 97/04861 ("Bionatec"). Applicants traverse the rejection.

In response to applicants' remarks of March 20, 2001, which are incorporated herein by reference, the Examiner alleges that (1) the claims "are not directed to any degree of

homogeneity," and (2) Bionatec discloses granules coated with an active agent, where the granules have a core that is 0.01 mm (10 μm) in diameter.

First, claim 1 specifically and clearly prescribes a neutral core, which is coated with the layer containing the plant substance. The claimed granule is thus not homogenous; it consists of at least two layers. It is axiomatic that the terms of a claim are not considered in a vacuum, but are interpreted in light of the specification when given their broadest ***reasonable*** interpretation. See MPEP § 2111.01, citing *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983). To allege that the claims do not prescribe any degree of homogeneity, the Examiner must interpret the neutral core as identical in composition to the layer containing the plant substance. However, the neutral core, defined at pages 3 through 4 of the specification, for example, cannot reasonably be interpreted as being identical to the layer that coats it. On the contrary, the claims prescribe that the neutral core is coated with a layer containing the plant substance. In fact, problems with prior devices in the art are solved by the invention within the framework of providing a neutral core over which the plant substance is coated. See page 1 through the middle of page 2 of the specification. Accordingly, the rejection is predicated on a legally erroneous interpretation of the claims.

Second, the neutral core of the claimed granule is between 200 and 1600 μm in diameter, whereas the cores of the particles disclosed in Bionatec are either 10 μm in diameter or are pollen grains about 2000 μm in diameter. See claims 11 and 12 of '861. These values fall outside the claimed range of core size; therefore, Bionatec cannot anticipate the claimed invention. Further, the Examiner has pointed to no teaching in Bionatec that would have motivated the artisan of ordinary skill in the art to select other core diameters that might fall within the claimed range. For both of these reasons, Bionatec neither anticipates nor renders obvious the claims at issue, and the rejection should be withdrawn.

(II) Claims 1, 2, and 4-9 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Jacob *et al.*, US Patent 5,733,551 ("Jacob"). Applicants traverse the rejection.

In response to applicants' remarks of March 20, 2001, which are incorporated herein by reference, the Examiner again alleges that the claims are not directed to any degree of homogeneity. Applicants traverse this allegation on the same grounds as made in the rejection over Bionatec above, which are herein incorporated by reference in their entirety.

The Examiner alleges that Jacob teaches each and every element of the claims at issue; however, applying the proper interpretation to the terms in the claims, it is clear that Jacob does not anticipate the claims. Jacob discloses a process of extrusion and spheronization to prepare an orally absorbable spheroid containing an active ingredient. That is, granules are prepared from a ***homogenous mass*** containing a plant substance that is extruded through a die and then spheronized (col. 5, at the Summary of the Invention). Jacob nowhere teaches or suggests depositing the liquified mass containing the plant substance onto a neutral core. Since the products obtained by Jacob's method are homogenous, they cannot anticipate the claimed invention. The rejection is thus improper and should be withdrawn.

(III) Claims 1, 2, 4, 5, and 16-20 are newly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Cingotti, U.S. Patent 5,427,800 ("Cingotti"). Applicants traverse the rejection.

The Examiner alleges that the granules taught by Cingotti anticipate the claimed invention; however, Cingotti does not use a neutral core having the claimed diameter. The disclosure cited by the Examiner refers to the size of the finished granules, not the size of the neutral core. In Example 1, for instance, Cingotti uses a silica core ("primary particle") with a diameter of 18 nm (0.018 μm; col. 3, line 52), which is then wetted with tincture to form the "coated granule" (col. 3, lines 54-55 and 60). The ***coated granule, not the neutral core***, is then gauged to a size of 1500 to 2000 μm and finally 500 μm (col. 3, lines 61-62 and 65; col. 2, lines 47-48 in general: "Once the granules are coated, these granules are gauged. . ."). In Example 4, the silica core is replaced with granules of microcrystalline cellulose having a diameter of 40-70 μm (col. 4, lines 57-61). This cellulose core is then wetted to form a coated particle (col. 4, lines 63-65). Because the cores in these formulations are not at least 200 μm in diameter, as prescribed in the present claims, Cingotti does not anticipate the claims.

Cingotti further teaches that these coated, gauged granules are mixed with microgranules and "adsorbed on or in" the microgranules (col. 2, lines 57-58). The microgranules have a diameter of between 100 and 1000 μm (col. 3, lines 1-2). The layer on the microgranules contains a plant substance, an excipient, ***and*** the coated granules. By contrast, the coating layer of the presently claimed invention consists of a plant substance and an excipient; it does ***not*** itself contain a coated granule. Since these layers are distinct, this embodiment of Cingotti also does not anticipate the claims.

Rejection under 35 U.S.C. § 103(a):

Claims 3, 6-8, 14, 15, and 21 are newly rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Cingotti and U.S. Patent 6,056,949 ("Menzi"), in view of Breitenbach *et al.*, U.S. patent 6,120,802 ("Breitenbach"). Applicants note that this rejection must apply to those claims from which the rejected claims depend, in view of the Examiner's mandate to examine the claimed invention as a whole. Thus, this rejection must apply also to claims 1, 4, 5, 11, and 13. Applicants traverse the rejection.

Cingotti does not teach or suggest the limitations of claims 1 and 11, from which all the other claims depend, *supra*. Menzi does not make up for the deficiencies of Cingotti by itself or in combination, for the reasons set forth below. Accordingly, dependent claims 3-8, 13-15, and 21 must also be allowed since they incorporate every element of independent claims 1 and 11. The rejection of claims 3-8, 13-15, and 21 thus should be withdrawn.

Menzi is relied upon for suggesting the incorporation of a flavorant comprising a plant extract. However, whereas the present invention claims neutral cores, the flavor and odor producing substances of Menzi represent active core ingredients. This is evident at column 1, lines 60-61, where Menzi teaches a process "characterized by spraying a flavorant or odorant emulsion ***into*** a core material." The resulting granules are clearly shown in Figure 1 as containing active ingredients inside the core. By contrast, the present invention uses neutral cores to carry the plant substance.

The Examiner relies on Breitenbach for its suggestion to use plasticizers, binders, and delaying agents, but the Examiner admits that it does not teach the use of a neutral core. In this regard, it does not correct the deficiencies of the combined teachings of Menzi and Cingiotti, neither of which teach or suggest the presently claimed neutral core, for the reasons given above. Accordingly, the proposed combination of references would not have made the claimed invention obvious, and the rejection thus should be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully urged that the present claims are in condition for allowance. An early notice to this effect is earnestly solicited. If any additional extensions of time are required for the filing of this paper, applicant expressly

petitions for such extensions and authorize the Commissioner to charge any deficiency to Deposit Account 19-0741.

Should there be any questions regarding this application, especially if the Examiner feels that he would benefit from further clarification of the invention, the Examiner is encouraged to contact the undersigned at the telephone number shown below.

Respectfully submitted,

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Date

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Marked-Up Version Showing Changes

1. (Twice Amended) Granules containing at least one plant substance, comprising a neutral core having a particle size of between 200 and 1600 μm coated with a layer ~~containing~~ consisting of the plant substance combined with a pharmaceutically acceptable excipient.